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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,711	04/08/2004	Larry A. Gilbertson	38-21(52967)B	1699

46795 7590 01/25/2007
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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/821,711

Applicant(s)

GILBERTSON ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/28/05;6/17/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-12 and 14-18, in the reply filed on 24 October 2006 is acknowledged. The traversal is on the ground(s) that it would not create an undue burden to conduct a search encompassing all of the claims. This is not found persuasive because the scope of the different inventions is not coextensive and would require different specific searches of the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 13 and 19-23 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 24 October 2006.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

4. The Examiner has required restriction between product and process claims. The Examiner considers pending claim 20 as directed to a process of using the elected product in the instant Application, and may be eligible for rejoinder if the elected invention is found to be allowable. Where applicant elects claims directed to the product, and a product claim is

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subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 2-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 2, line 2, "linked to a plant cell non-lethal negative selectable marker gene" renders the claim indefinite because it is unclear if this limitation is directed to the same feature at line 4 of claim 1, or is directed to a different "marker gene" not specifically recited in claim 1. Hence, the metes and bounds of the claim are unclear. Claims 3 and 4 are also indefinite.

At claim 4, line 1, the limitation "said promoter expresses" renders the claim indefinite because a promoter does not express anything, its function is to induce expression of an operably linked coding region. Hence, the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4 and 9-11 are rejected under 35 U.S.C. § 102(e) as being anticipated by Heim *et al* (U.S. Patent Application Publication US 2003/0188345 A1, filed 28 June 2001).

Heim *et al* disclose a DNA plasmid comprising a T-DNA comprising an *Agrobacterium* Ti plasmid first border region linked to at least one transgene linked to an *Agrobacterium* Ti plasmid second border region, and located in the DNA plasmid outside of the T-DNA is a plant expression cassette comprising a plant cell non-lethal negative selectable marker gene linked to a vector backbone DNA at claim 7, Figure 4 and page 4, left column, paragraph 0025. Heim *et al* specifically disclose integrating the *codA* gene from *E. coli* on the vector side of the left T-DNA border that permits a combined positive/negative selection. Figure 4 discloses using the constitutive CaMV 35S promoter operably linked to such a gene on said vector side. Figure 4 discloses the use of the positive selectable marker gene, *Pat* that produces phosphinothricin herbicide resistance to the transformed cell. Phosphinothricin herbicide resistance is a desirable transgene to introduce into a transgenic plant, and was well known in the art as such at the time of Applicants' invention. The instant application discloses use of the same *codA* gene in the vector backbone DNA at page 30, line 12. Hence, Heim *et al* have previously disclosed all of the claim limitations.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

10. Claims 5-8, 12 and 14-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Heim *et al* (U.S. Patent Application Publication US 2003/0188345 A1, filed 28 June 2001) in view of Lange *et al* (U.S. Patent 5,939,539) and Ebinuma *et al* 1997 (Proc. Natl. Acad. Sci. USA 94: 2117-2121).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicants teach that the problem to be solved by the claimed invention is that "The vector backbone DNA contains various plasmid maintenance genetic elements, e.g., origin of replications, bacterial selectable marker genes, and other DNA fragments not desirable in commercial crop products for regulatory issues." at page 2, lines 10-13 of the specification.

Heim *et al* teach that it is undesirable to introduce vector sequences, for example bacterial resistance genes also transferred into the genome of the plants in addition to the T-DNA with the desired transgenic nucleotide sequences (page 1, right column, 1st paragraph). Hence, the prior art had identified the same problem to be solved that has been asserted by Applicants' teachings.

Heim *et al* teach a DNA plasmid comprising a T-DNA comprising an *Agrobacterium* Ti plasmid first border region linked to at least one transgene linked to an *Agrobacterium* Ti plasmid second border region, and located in the DNA plasmid outside of the T-DNA is a plant expression cassette comprising a plant cell non-lethal negative selectable marker gene linked to a vector backbone DNA; at claim 7, Figure 4 and page 4, left column, paragraph 0025. Heim *et al* specifically teach integrating the *codA* gene from *E. coli* on the vector side of the left T-DNA border that permits a combined positive/negative selection. Figure 4 teaches using the constitutive CaMV 35S promoter operably linked to such a gene on said vector side. Figure 4 teaches the use of the positive selectable marker gene, *Pat* that produces phosphinothricin herbicide resistance to the transformed cell. Phosphinothricin herbicide resistance is a

desirable transgene to introduce into a transgenic plant, and was well known in the art as such at the time of Applicants' invention.

Heim *et al* do not teach a DNA plasmid wherein the plant expression cassette encoding a plant cell non-lethal negative selectable marker gene outside of the T-DNA encodes a plant hormone biosynthetic pathway gene, a plant hormone degradative gene, a plant hormone biosynthetic pathway substrate-diverting gene, or a plant hormone signaling gene.

Lange *et al* teach a plant hormone degradative/modifying gene, a gibberellin 20-oxidase that when expressed in a transgenic plant produces increased stem extension and leaf expansion compared to a wild-type plant (see column 18). Hiroyasu *et al* teach using the isopentenyl transferase gene (*ipt*) as a non-lethal negative selectable marker gene because expression in a transgenic plant produces loss of apical dominance and the inability to root in culture due to overproduction of cytokinins (page 2117, right column, 2nd paragraph). Hence, those of ordinary skill in the art were well aware of how to use non-lethal negative selectable marker genes in plant transformation methods at the time of Applicant's invention.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Heim *et al* to use other negative selectable marker genes in the DNA plasmid, such as those taught by others in the prior art; Lange *et al* or Hiroyasu *et al*. Given the success of those of ordinary skill in the art in expressing genes that can be used as a non-lethal negative selectable marker gene in transgenic plant, one would have a reasonable expectation of success. Heim *et al* were

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successful in distinguishing transgenic plants that incorporated DNA out side of the T-DNA, hence the DNA plasmid taught worked. Heim *et al* motivate those of ordinary skill in the art to use other selectable markers, including non-lethal negative selectable marker gene outside of the T-DNA.

Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'David H. Kruse', written in a cursive style.

David H. Kruse, Ph.D.
18 January 2007

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13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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